Amendment #1
to RFP-NIH-NIAID-DAIDS-02-07

"HIV Vaccine Development Resources"

Amendment to Solicitation No.:	NIH-NIAID-DAIDS-02-07
Amendment No.:	1
Amendment Date:	June 26, 2001
RFP Issue Date:	April 30, 2001
Issued By:	Jacqueline C. Holden Senior Contracting Officer NIH/NIAID Contract Management Branch 6700-B Rockledge Drive Room 2230, MSC 7612 Bethesda, Maryland 20892-7612
Point of Contact:	Janet M. Mattson, Contract Specialist
Name and Address of Offeror:	To All Offerors

The above referenced solicitation is hereby amended as follows to respond to questions presented by recipients of this RFP:

Question 1. I am completing the Technical Part of the Proposal but find it awkward to consider a Business Part without a Task Order. How is one expected to figure costs with any true measure of effort?

Answer 1. Please refer to the "Notes To Offerors - NOTE #1 TO OFFERORS." The paragraph following the bullet list of items states:

"The number and types of products to be developed cannot be specified at this time. For the purposes of responding to this RFP, the Offeror shall describe in some detail its experience with the development/optimization of a specific vaccine, preferably a biological product, regardless of the applicability of that particular product to an HIV vaccine.....The offeror is requested to propose a detailed plan for producing a pilot lot through to the final form to be delivered for clinical trails of any one or more of the four vaccine Categories.

The Offeror shall submit a plan for each vaccine Category for which they are applying. If the Offeror does not have a specific vaccine to propose for production in one of these categories, they should use the examples below to construct a plan and proposed budget. **(Four different samples are listed with dosages.)**

a) Recombinant protein – 1000 doses of rGP120, formulated with alum adjuvant at 200 ug/dose. Assume that the HIV strain is a primary NSI strain.

b) DNA vaccine – 1000 doses of a clinical grade recombinant plasmid with sequence(s) of relevant genes.

c) Vector-based vaccine. Live recombinant virus - 10,000 doses of recombinant vaccinia expressing an HIV env gene from one promoter and an HIV gag gene from another, to be delivered at 10^8 pfu/dose. Assume that the HIV inserts are stable, and the recombinant vector has shown good growth properties in a variety of standard mammalian cell substrates. (Alternatively, propose a bacterial vector based vaccine)

d) Virus-like particle – 1000 doses at 100 ug p24/dose.

For each vaccine Category, the Offeror shall propose production, purification and characterization methods and a timeline for obtaining completion of each pilot lot, with sufficient data generated for IND submission. Potential pitfalls and back-up plans shall be included. The Offeror shall include a statement of its maximum capacity for production of each vaccine lot. Include cost estimates in the form of a detailed budget proposal for performing all the activities listed in the Statement of Work."

Question 2. If we are proposing the production of a DNA vaccine what is the amount of DNA/dose?

Answer 2. Propose an amount of 100 ug/dose with 1000 doses of a clinical grade of recombinant plasmid with sequence(s) of relevant genes giving 1 gram of material.

- Except as provided herein, all terms and conditions of this RFP remain unchanged and in full force and effect.
- The hour and date specified for receipt of offers REMAINS: **July 6, 2001, 4:00 PM, EST**.
- Offerors must acknowledge receipt of this Amendment #1, on each copy of the proposal submitted.

Failure to receive your acknowledgment of this amendment may result in the rejection of your offer.

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